

EXHIBIT C

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P R O C E E D I N G S

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3 THE VIDEOGRAPHER: Good morning. This is
4 the video deposition of Robert Niemann taken by
5 counsel for the Defendant in the matter of In Re
6 Pharmaceutical Industry Average Wholesale Price
7 litigation in the United States District Court for
8 the district of Massachusetts, MDL number 1456, Civil
9 Action Number 01-CV-12257-PBS, held in the offices of
10 Centers for Medicare & Medicaid Services at 7111
11 Security Boulevard, Baltimore, Maryland on this date
12 Friday, September 14th, 2007, at the time indicated
13 on the video screen, 9:18 a.m.

14 My name is Ellen Hebert. I'm the legal
15 video specialist. The court reporter is Sue
16 Ciminelli. We are employed by Henderson Legal
17 Services. Counsel will now introduce themselves and
18 the parties they represent after which the court
19 reporter will swear in the witness.

20 MR. COOK: Christopher Cook for Abbott
21 Laboratories for Jones Day. I'm accompanied by
22 project assistant Emily Watson.

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1 MS. REID: Sarah Reid from Kelley Drye on
2 behalf of the Day Companies and the DOJ cases and
3 also on behalf of Day and Mylan at cross notice
4 states.

5 MS. MCGEE: Jennifer McGee, representing
6 Aventis Pharmaceutical and Sanofi.

7 MR. JONES: Scott Jones from Locke Liddell
8 from Schering & Warrick.

9 MR. HOVAN: Aaron Hovan from Kirby
10 McNerney, representing New York City and all New York
11 counties other than Nassau and Orange.

12 MR. WILSON: Joe Wilson with Cotchett,
13 Pitre & McCarthy, on behalf of Ven-A-Care.

14 MS. STAFFORD: Leslie Stafford of the
15 Centers for Medicaid Services.

16 MS. OBEREMBT: Laurie Oberembt from the
17 United States Department of Justice representing the
18 United States.

19 THE VIDEOGRAPHER: Will the attorneys on
20 the phone --

21 MR. BATES: I'm Roger Bates representing
22 the State of Alabama.

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1 MR. GORTNER: Eric Gortner, representing
2 from Kirkland & Ellis representing Boehringer
3 Ingelheim and Roxane Laboratories Inc.

4 MR. ARCHIBALD: Jeff Archibald,
5 representing the attorney generals for the states of
6 South Carolina, Wisconsin, Kentucky, Iowa, and Idaho.

7 MS. MILLER: This is Mary Miller,
8 assistant attorney general representing the State of
9 Florida in the cross notice deposition cross noticed
10 by Mylan.

11 MS. KAWATRA: Sandhya Kawatra from Hogan &
12 Hartson representing Bristol-Myers Squibb Company.

13 MS. KATCHERIAN: Amy Katcherian, White &
14 Case LLP, representing Sandoz, Inc.

15 MR. GLASER: Deputy attorney general Randy
16 Glaser with the California Attorney General's Office

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2 A. That's what it says.

3 Q. Or I assume other drugs, it says these
4 drugs in the plural, correct?

5 A. That's what it says, yes, to price these
6 drugs.

7 Q. Was it your understanding that it was the
8 policy of HCFA that carriers were not permitted to
9 obtain invoices and try to establish an estimated
10 acquisition cost?

11 A. Well, I forgot that. But now that I'm
12 reading this, I do seem to remember, I remember there
13 were OMB requirements about data collection from more
14 than a certain threshold number of people, and there
15 was a process to go through in order to have that
16 data collection approved and I do vaguely, not the
17 details but I vaguely remember this coming into play
18 with EAC so that, that seems to be what they are
19 getting at here is that the data collection
20 requirement had not been cleared through OMB. I
21 think they said information collection is probably
22 what they used.

00169

1 Q. Do you recall whether HCFA made efforts to
2 satisfy those requirements to conduct surveys and
3 establish estimated acquisition costs?

4 A. I don't.

5 Q. What was your understanding of what
6 estimated acquisition cost would have represented had
7 HCFA implemented that, that provision of the
8 regulation?

9 A. Well, I would have -- I take that term at
10 its literal meaning. I mean, it would, it would have
11 been an estimate of what the cost was to the
12 physician who is billing us, what that physician
13 paid.

14 Q. And was it your understanding that had
15 HCFA implemented that aspect of the regulation that
16 HCFA would have attempted to establish it drug by
17 drug?

18 MS. OBEREMBT: Objection.

19 THE WITNESS: I --

20 BY MR. COOK:

21 Q. I guess there is only one way to do it, it
22 would have to be on a drug by drug basis correct?

00170

1 A. I guess that's true. I guess so.

2 Q. And in the Exhibit 310 which appears to
3 be, would you agree with me, Dr. Steffen's response
4 to the July 1996 letter? The first paragraph in this
5 letter to Ms. Merrill states "we agree that the
6 central office should be made aware of the issues
7 that we discussed, namely the great difference
8 between the EAC and the AWP the barriers to obtaining
9 the EAC." Do you understand in that letter the EAC
10 referred to acquisition costs as indicated in the Re
11 line?

12 A. I don't but oh, right. Yes.

13 Q. Would you have been the individual within
14 the central office who you assume would be made aware
15 of the great difference between acquisition costs and
16 the AWP for Medicare reimbursable drugs?

17 A. Yes.

18 Q. Did you participate in to your

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19 recollection this conversation between Ms. Merrill
20 and Dr. Steffen?

21 A. I don't remember that I did. No.

00171

22 Q. You'll see a little bit farther down the

1 page Dr. Steffen calculates some, some numbers for
2 Zoladex, in particular and calculates that for
3 provider with --

4 A. Can I -- something is troubling me.

5 Q. Please do.

6 A. Of a former, when you asked me the only
7 way to implement AEC would have been on a drug by
8 drug basis and I said I guess so because I'm not used
9 to thinking about these things and thinking them
10 through.

11 Q. Oh no please?

12 A. I don't think that would be true.

13 Q. How would one do it?

14 A. No. I have no idea how it could be done
15 and the range of possibilities.

16 Q. Uh-huh?

17 A. But I would think the EAC could be used in
18 combination to come up with a price for a HCPCS code
19 that represented a range of suppliers for a drug.
20 All I'm getting at is I didn't want to be locked into
21 speculating that the only way EAC could be used was
22 on a specific drug by drug basis. I don't want to

00172

1 agree to that because I don't know that to be true.

2 Q. Well, between 1993 and 1997, when you were
3 the program, the policy analyst who was response for
4 drug payment issues at Medicare, the regulation was
5 still extant, correct that had EAC as one of the
6 options, correct?

7 A. Yes.

8 Q. Did you consider any of the ways in which
9 Medicare could have implemented the EAC option?

10 A. I don't remember that that ever, we never
11 got that far.

12 Q. And how so?

13 A. Well, for the reasons we are saying, that
14 either because of resources or because the
15 information collection hurdle was never overcome, so
16 we didn't have the data so I don't remember us ever
17 having to consider that.

18 Q. So as I understand the position then of
19 when I say the position, I don't mean the poll
20 circumstances I mean the position that HCFA found
21 itself in between 1991 and 1997 was it was paying
22 with a Medicare allowable based upon AWP, correct?

00173

1 A. Uh-huh.

2 Q. It did not have, HCFA did not have in
3 place any limitations on provider's charges, it would
4 have prevented providers from charging more than
5 their cost or more than a percentage over their cost,
6 correct?

7 A. It's how I remember it.

8 Q. Right. That HCFA had one alternative of
9 estimated acquisition costs that would have allowed
10 it if implementable to gauge the Medicare allowable
11 amount to something closer than to actual acquisition
12 cost, correct?

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13 A. Yes.
 14 Q. Was it your sense that HCFA as an
 15 organization wanted to move towards EAC?
 16 MS. OBEREMBT: Objection.
 17 THE WITNESS: I don't know how to answer
 18 that. I mean, how many people would have been
 19 involved in this and what their opinions would have
 20 been, I never polled anybody.
 21 BY MR. COOK:
 22 Q. Okay. Was there anybody within the agency

00174

1 who preferred to stay with AWP rather than go to EAC
 2 in your memory?
 3 MS. OBEREMBT: Objection to the extent
 4 you're asking him about deliberative process
 5 conversations.
 6 THE WITNESS: So what do I do?
 7 MS. OBEREMBT: Why don't we take a break
 8 and let me find out what he was going to say.
 9 MR. COOK: Okay.
 10 THE VIDEOGRAPHER: This marks the end of
 11 tape three in the deposition of Robert Niemann. The
 12 time is 13:54:38.
 13 (Recess.)
 14 THE VIDEOGRAPHER: This marked the
 15 beginning of tape four in the deposition of Robert
 16 Niemann. Going back on the record. The time is
 17 14:02:57.
 18 MS. OBEREMBT: Chris, I understand your
 19 question to be asking him about discussions he had
 20 with others at CMS about what the drug policy should
 21 be.
 22 MR. COOK: Yes.

00175

1 MS. OBEREMBT: So on that basis I'm going
 2 to instruct him not to answer because it does go to
 3 deliberative process.
 4 MR. COOK: And just so I know the
 5 parameters of the instruction not to answer, to the
 6 extent that there was anybody within CMS who actually
 7 preferred to go with, stay with AWP knowing that AWP
 8 exceeded acquisition costs rather than going to EAC
 9 which would approximate acquisition cost you're going
 10 to instruct him not to answer those questions?
 11 MS. OBEREMBT: I'm going to instruct him
 12 not to disclose discussions he had about what a
 13 policy should be because that goes to the heart of
 14 the deliberative process privilege.
 15 MR. COOK: Well, I'll ask him a question
 16 and you can instruct him not to answer because I want
 17 this one to be, I want to know what I can ask and
 18 what I can and I'll just go through the questions and
 19 you can instruct him not to answer them if you think
 20 that they are not, that they are not permissible.
 21 BY MR. COOK:
 22 Q. Mr. Niemann, you understood that there

00176

1 were essentially two options available to the
 2 Medicare program between 1991 and 1997 for
 3 establishing what the Medicare allowable should be or
 4 would be for physician administered drugs, correct?
 5 It's restating an earlier question. I know.
 6 A. On the allowable, it's really technically

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7 I guess three.

8 Q. Okay?

9 A. Because we pay the lower of the actual
10 charge on the thing.

11 Q. All right. But there will always be a
12 charge in connection with the claims for physician
13 administered drug correct?

14 A. Right.

15 Q. And the question is going to be if that
16 charge exceeds a certain amount, will you pay the
17 charge or that certain amount, correct?

18 A. Right.

19 Q. So if, for example, the charge is, well I
20 guess the last data point in any claim would be the
21 actual cost to the physician, correct, although
22 that's not one that you have.

00177

1 A. Well, all I was saying is that there are
2 three.

3 Q. Right?

4 A. Components to the decision.

5 Q. Correct. And if we were to look at an
6 individual claim, there would be four, there would be
7 three data points, one would be the physician has an
8 actual cost, correct?

9 A. Right.

10 Q. You don't know what that is?

11 A. Right.

12 Q. The physician states a charge to the, the
13 program, correct?

14 A. Right.

15 Q. You Doe know what that number is?

16 A. Yes.

17 Q. And the program through its carriers has
18 an allowable amount which the charge may not exceed
19 or will be disallowed to the extent that it exceeds
20 the allowable, correct?

21 A. They wouldn't pay any more than that.

22 Q. Right. There were two options for the

00178

1 program to set what the allowable amount would be
2 under the Medicare regulations as they existed
3 between 1991 and 1997, correct?

4 A. Yes. I would just say I recognize you're
5 struggling. The maximum allowable.

6 Q. Precisely?

7 A. Because it would never exceed the actual
8 charge.

9 Q. Precisely.

10 A. I get the drift of what you're saying.

11 Q. And the two options for setting the
12 maximum allowable would be 100 percent of the maximum
13 allowable as published in Red Book or other compendia
14 right?

15 A. Or other compendia.

16 Q. That's right?

17 A. I think that's what it said.

18 Q. The other option under the Medicare
19 program under the regulations was to establish an
20 estimated acquisition cost, correct?

21 A. Yes.

22 Q. Unlike the average wholesale price, that

00179

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1 would be a calculated number, correct?

2 A. Yes.

3 Q. It would be calculated by HCFA?

4 A. I --

5 Q. Or the carriers?

6 A. Yes. I think the carriers.

7 Q. By either HCFA for its agent?

8 A. Right.

9 Q. Would calculate that number correct?

10 A. Yes.

11 Q. And do you have an understanding of how
12 hick have or its agents would calculate that number?

13 A. No.

14 Q. Do you have an understanding of what that
15 number would represent?

16 A. Oh as I said before, I think it would be
17 the best estimate of what the physician's acquisition
18 cost was but I don't necessarily mean that individual
19 physician.

20 Q. And in choosing between the published
21 average wholesale price and the best estimate of what
22 the physician's acquisition cost was, that is

00180

1 estimated acquisition cost, did you have any
2 discussions within the agency about which option to
3 use?

4 MS. OBEREMBT: You can answer that. You
5 can tell him whether or not you had discussions about
6 options.

7 THE WITNESS: Yes.

8 BY MR. COOK:

9 Q. And were there individuals who advocated
10 for staying with the average wholesale price?

11 MS. OBEREMBT: I'll direct you not to
12 answer that on the grounds of deliberative process.

13 MR. COOK: So I can't get the process of
14 whether there were individuals who took that
15 position.

16 MS. OBEREMBT: That's right. Because
17 because that goes to the substance of the
18 discussions. Your previous went to whether or not
19 there were discussions now you're getting into the
20 substance so I have to object.

21 BY MR. COOK:

22 Q. Were there individuals who advocated using

00181

1 the estimated acquisition cost?

2 MS. OBEREMBT: Objection. Grounds of
3 deliberative process. I'll direct you not to answer.

4 BY MR. COOK:

5 Q. Who participated in these discussions?

6 A. It would have been my division director,
7 me and the deputy group director. Legislative
8 personnel on our legislation staff. I don't mean, I
9 don't mean staffers on the Hill. I mean our people.
10 People like that.

11 Q. When did these conversations take place?

12 A. I guess off and on for the whole time that
13 I was involved in it. Maybe not, not too early. I
14 don't have that clear recollection of --

15 Q. As a matter of fact, for the entire time
16 period where estimated acquisition cost was an option
17 available to HCFA, HCFA in fact established its

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18 maximum allowable cost based upon average wholesale
19 price, correct?

20 A. Yes. Except where a carrier may have done
21 it sooner than when this all came about with OMB and
22 the information collection.

00182

1 Q. In any of these discussions, do you recall
2 any participant ever expressing to you the belief
3 that by paying average wholesale price Medicare
4 program was reimbursing physicians at their actual
5 acquisition cost?

6 MS. OBEREMBT: Objection on the grounds of
7 deliberative process. I'll instruct you not to
8 answer.

9 BY MR. COOK:

10 Q. Has anybody ever in your time at HCFA
11 expressed to you the belief that average wholesale
12 price is a reliable indicator of the acquisition cost
13 to physicians for drugs?

14 MS. OBEREMBT: I'm going to object to the
15 extent you're asking him about conversations he had
16 that involve deliberative processes of the agency.
17 I'm going to instruct you not to answer that too.

18 BY MR. COOK:

19 Q. In any of these conversations relating to
20 the possibility of abandoning AWP and going to
21 estimated acquisition cost, did any of the
22 individuals that you've described ever raise concerns

00183

1 about what the consequences would be to beneficiaries
2 access to care or other program goals of going to
3 EAC?

4 MS. OBEREMBT: Objection on the grounds of
5 the deliberative process privilege. I'll instruct
6 you not to answer.

7 BY MR. COOK:

8 Q. What position did you take about using
9 average wholesale price or the estimated acquisition
10 cost?

11 MS. OBEREMBT: Objection on the grounds of
12 deliberative process. I'll instruct you not to
13 answer.

14 BY MR. COOK:

15 Q. Did politics ever play a role in the
16 Medicare program's decision to continue to use
17 average wholesale price rather than use estimated
18 acquisition costs to establish its maximum allowable
19 payment amount for drugs?

20 MS. OBEREMBT: Objection to the extent
21 you're asking him about discussions with agency
22 personnel where a policy decision was made. I have

00184

1 to instruct you not to answer that too, I think.

2 BY MR. COOK:

3 Q. At various points in time between 1991 and
4 1997 without telling me about what discussions were
5 made, is it fair to say the decision was made to stay
6 with AWP and not go to estimated acquisition cost?

7 A. Well that was the stated, that was the
8 regulation.

9 Q. Well the regulation allowed both?

10 A. Oh, allowed both?

11 Q. Yes?

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12 A. I'm sorry would you repeat.
 13 Q. I assume -- at various points in time when
 14 the possibility of going from AWP to EAC was
 15 considered?

16 A. Right.
 17 Q. In fact, HCFA continued to use AWP,
 18 correct?

19 A. It did.
 20 Q. All right. After discussions relating to
 21 a possible change and after it was decided to remain
 22 with AWP, did you ever have any discussions with any

00185

1 other personnel at HCFA about the decision that had
 2 already been made to stay with AWP and whether that
 3 was a good idea?

4 MS. OBEREMBT: Objection because again I
 5 think you don't have a specific point demarche ated
 6 and his post policy discussions may be predecisional
 7 to subsequent policies so I can't, I'm going to
 8 object again on deliberative process and instruct you
 9 not to answer.

10 BY MR. COOK:

11 Q. Did you ever have any discussions with
 12 anyone outside of HCFA about whether Medicare could,
 13 should continue to pay based upon AWP or should use
 14 some other methodology for establishing the maximum
 15 allowable amount?

16 A. That I don't remember. Outside of HCFA.

17 Q. Yes?

18 A. I don't remember.

19 Q. Say someone with Congress?

20 A. That would have occurred. I can't
 21 remember specifically, but that would have occurred.

22 Q. Without the specifics?

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1 A. Not a member of Congress but the staffer.

2 Q. The staffer. Do you remember generally
 3 what the subject matters were relating to the
 4 possible departure from AWP as a methodology in your
 5 conversations with congressional staffers?

6 A. I'm sorry. What was the -- what's the
 7 crux of that? Do I remember what.

8 Q. Do you remember generally what the subject
 9 matters of those conversations were?

10 A. Subject matters?

11 Q. Let me ask it a little bit easier. Do you
 12 remember anything at all about your conversations
 13 with congressional staffers?

14 A. That is easier. Not much, but it would,
 15 it would have been the IG information and some kind
 16 of methodology to pay a fair price.

17 Q. Do you recall whether you or anybody else
 18 from HCFA was advocating a change in the methodology
 19 to these congressional staffers?

20 MS. OBEREMBT: You can answer that.

21 THE WITNESS: Was anybody advocating a
 22 change to what the staffers were recommending? I'm

00187

1 sorry.

2 BY MR. COOK:

3 Q. The status quo was that?

4 A. AWP and we never implemented AEC. That
 5 was the status quo.

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6 MS. OBEREMBT: Are you asking him in his
7 conversations with people on the Hill?

8 MR. COOK: Yes.

9 MS. OBEREMBT: Okay. So focus your answer
10 on just conversations you had with people on the
11 Hill, what was said.

12 THE WITNESS: Not HCFA people but
13 staffers.

14 MS. OBEREMBT: Right.

15 BY MR. COOK:

16 Q. Right. Did you or anybody else from HCFA
17 in these conversations with staffers on the Hill ever
18 advocate a change in the methodology away from AWP?

19 A. Yes. Yes.

20 Q. What?

21 MS. OBEREMBT: Objection. That goes to a
22 deliberative process issue since you're asking him

00188

1 why they would have expressed that opinion to the
2 staffers.

3 MR. COOK: So the decision was whether to
4 talk to Congress.

5 MS. OBEREMBT: You can ask him what was
6 said to the staffers, but you can't ask him why that
7 was said because that does go to deliberative process
8 information okay.

9 MR. COOK: Just so I understand and I've
10 got the record straight. Exactly which decision is
11 that deliberation predecisional to?

12 MS. OBEREMBT: To decisions made within
13 the agency to either continue with the existing
14 policy or to proceed with change in policy so why
15 don't don't you ask him what he said to the staffer
16 or was he present in any other HCFA meeting with a
17 congressional staffer.

18 BY MR. COOK:

19 Q. Did you express to the congressional
20 staffers why it was that HCFA was advocating a change
21 in the methodology by which Medicare paid for
22 physician administered drugs?

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1 A. Yes. I'm sure I would have expressed the
2 reason.

3 Q. And what was that reason?

4 A. It would have been the IG reports if the
5 fact that, that at least some of the drugs under the
6 AWP policy were, were, we were paying too much.

7 Q. When you say too much, can you quantify
8 that for me?

9 A. No, I can't quantify it because of the
10 reason you have cited that it wasn't a single amount
11 with every drug. It varied.

12 Q. When you say too much, is that a dollar
13 amount, a percentage?

14 A. I remembered that being some concern. And
15 remember being released that I wasn't the one who had
16 to pick the number. I mean it's a judgment call
17 what, like whether to knock off 5 percent or 15
18 percent, that's a judgment call.

19 Q. And 10 percent of a \$400 drug is a lot
20 more than a thousand percent of a \$2 drug, correct?

21 A. Indeed it is.

22 Q. Did you express to Congress any position